UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,428	12/15/2003	Alfred J. Moo-Young	CBR 3.0-017 CONT	3967

530 7590 12/05/2006

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
CAPPS, KEVIN J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,428	MOO-YOUNG ET AL.	
	Examiner	Art Unit	
	Kevin Capps	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/06; 4/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This Office Action is in response to the Remarks, Amendments, and Declaration filed on September 6, 2006. Claims 1, 3-16, and 23 are pending and examined on the merits herein.

2. As discussed further below, the Declaration Under 37 CFR 1.131 is insufficient to overcome the rejection of claims 1 and 3-16 under 35 USC § 103 over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735) and claim 23 under 35 USC § 103 over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735) as applied to claims 1 and 3-16, and further in view of Moo-Young et al. (US 5,733,565). Therefore, the rejections are maintained and Applicant's arguments are addressed below.

3. The rejection of claims 1, 3-6, and 13-16 under 35 USC § 103 over Jain et al. (US 5,780,050) in view of Bardin et al. (US 5,342,834) is maintained. Applicant's arguments are addressed below.

4. The rejection of claim 23 under 35 USC § 103 as being unpatentable over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735) as applied to claims 1 and 3-16, and further in view of Moo-Young et al. (US 5,733,565) is maintained. Applicant's arguments are addressed below.

Response to Amendment

5. The declaration filed on September 9, 2006, under 37 CFR 1.131 has been considered but is ineffective to overcome the Reed et al. reference (WO 97/29735). Specifically, the Declaration must be signed by all of the inventors or must contain a showing that the inventor who did not sign did not contribute to the claimed invention. See MPEP § 715.04.

6. It is also noted that, although Applicant states that the date of the of the meeting on the document submitted as Exhibit A has been blacked out, the date still remains on the document. Further, this date predates the earliest priority date of the instant Application by more than one year.

Information Disclosure Statement

7. The information disclosure statement (IDS) filed on June 27, 2006, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS is being considered by the Examiner.

8. Also, the IDS submitted on April 15, 2004, was acknowledged and considered in the previous Office Action. However, the signed IDS was not returned to the Applicant. This IDS is being included along with this action.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1 and 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735).

12. Bardin et al. teach, "A method for providing androgen hormone supplementation to a human male patient...comprising administering...7α-methyl-19-nortestosterone...wherein the testosterone derivative is administered...transdermally in an amount of from 5 to 10 μg/kg of body weight." (claim 4). Transdermal administration of from 5 to 10 μg/kg of body weight of 7α-methyl-19-nortestosterone in the method of Bardin et al. translates to a dose of 350 to 700 μg for a 70 kg patient. The amounts delivered in bioavailable form from the instantly claimed compositions overlap the range of amounts of 7α-methyl-19-nortestosterone delivered by the instantly claimed dosage form (400 to 1600 μg).

13. Bardin et al. do not teach the transdermal dosage form used in the method.

14. Reed et al. teach transdermal drug delivery systems for the delivery of active substances (claim 1; abstract). Reed et al. teach suitable dosage forms for transdermal delivery of the active agents, including ointments, creams, lotions, gels, sprays, and patches (p. 7, lines 6-20). Reed et al. teach suitable vehicles for transdermal delivery of active compounds which are well-known and have been described in various US Patents (p. 7, lines 6-20). Reed et al. teach that 7α-methyl-19-nortestosterone is suitable for transdermal delivery in the well-known formulations.

15. It would have been obvious to the person of ordinary skill in the art at the time of invention to formulate 7α-methyl-19-nortestosterone in the transdermal delivery devices taught by Reed et al. in amounts sufficient to deliver the preferred doses taught by Bardin et al. to arrive at the instantly claimed invention.

16. The person of ordinary skill in the art would have been motivated to formulate 7α-methyl-19-nortestosterone in the transdermal delivery devices taught by Reed et al. at amounts sufficient to deliver the doses taught by Bardin et al. because Bardin et al. teach that the herein-claimed dose of 7α-methyl-19-nortestosterone is effective for androgen hormone supplementation in transdermal systems, and Reed et al. suggests various transdermal delivery systems which can be used to transdermally deliver active compounds. The person of ordinary skill in the art would have expected success because Reed et al. teach that 7α-methyl-19-nortestosterone is suitable for incorporation into the well-known transdermal delivery systems.

17. Although Bardin et al. and Reed et al. do not disclose the flux of 7α-methyl-19-nortestosterone in the transdermal delivery systems, the flux is an inherent property of

the transdermal delivery dosage form comprising 7α-methyl-19-nortestosterone which is rendered obvious by the teachings of Bardin et al. and Reed et al. See MPEP § 2112.01, paragraph I, which states, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established," (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)), and, "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Also, see MPEP § 2112.01, paragraph II, which states, "'Products of identical chemical composition can not have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)."

18. Bardin et al. and Reed et al. also do not disclose the herein-claimed preferred weight percentage of 7α-methyl-19-nortestosterone in the transdermal delivery system. Applicant's attention is directed to *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) which states, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP § 2144.05, "II. Optimization of Ranges". Formulations for the transdermal delivery of 7α-methyl-19-nortestosterone are suggested by Bardin et al.

and Reed et al. Thus, optimization of the weight percent of 7α-methyl-19-nortestosterone in the well-known transdermal delivery systems in order to achieve a dose that is substantially close to the dose taught by Bardin et al. is not considered inventive because it is a matter of routine experimentation for the ordinary skilled artisan.

19. The submission of the Declaration by Dr. Bardin averring that at the time of the Bardin et al. Patent application, no work had been done on transdermal delivery of 7α-methyl-19-nortestosterone, is acknowledged. However, "a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103". The Bardin et al. Patent is sufficient motivation for the person of ordinary skill in the art to look for references which teach known formulations for transdermal delivery of 7α-methyl-19-nortestosterone. Upon examining the Reed et al. document, the person of ordinary skill in the art would expect that 7α-methyl-19-nortestosterone could be formulated in the transdermal delivery systems exemplified by Reed et al. to deliver the doses taught by Bardin et al. because Reed et al. teach that 7α-methyl-19-nortestosterone can be formulated as such.

20. Claims 1, 3-6, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US 5,780,050) in view of Bardin et al. (US 5,342,834).

21. Jain et al. teach a patch device for transdermal delivery of androgen sex hormones with a 3-keto-4-en functional group, including methyl testosterone (claim 8; col. 4, line 49-col. 5, line 15). 7α-methyl-19-nortestosterone is an androgen sex

hormones with a 3-keto-4-en functional group. Jain et al. exemplify a transdermal patch comprising 2 weight percent of testosterone (Example 7).

22. Jain et al. do not teach 7α-methyl-19-nortestosterone as a preferred sex hormone for use in the patches. Jain et al. do not teach the herein-claimed dose of 7α-methyl-19-nortestosterone in the patch.

23. As discussed above, Bardin et al. teach transdermal delivery of 7α-methyl-19-nortestosterone at a dose which overlaps the herein-claimed dose.

24. It would have been obvious to the person of ordinary skill in the art at the time of invention to formulate 7α-methyl-19-nortestosterone in the patch of Jain et al. at the dose taught by Bardin et al. to arrive at the instantly claimed invention.

25. The person of ordinary skill in the art would have been motivated to formulate 7α-methyl-19-nortestosterone in the patch of Jain et al. at amounts sufficient to deliver the preferred doses taught by Bardin et al. with a reasonable expectation of success because Jain et al. generally teach formulation of methyltestosterones and androgen sex hormones in patches for transdermal delivery, and Bardin et al. teach that 7α-methyl-19-nortestosterone a preferred androgen for use in transdermal patches for providing sex hormone supplementation.

26. As discussed above, although the references do not discuss the flux of 7α-methyl-19-nortestosterone in the transdermal patches, this is an inherent property of the transdermal patches, which are rendered obvious by the combined teachings of the cited references. As is also stated above, optimization of the weight percent of 7α-methyl-19-nortestosterone in the patches is not considered inventive because it is within

the purview of the ordinary skilled artisan to arrive at the weight percentage needed to deliver the doses taught by Bardin et al. through routine experimentation.

27. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735) as applied to claims 1 and 3-16 above, and further in view of Moo-Young et al. (US 5,733,565).

28. Bardin et al. in view of Reed et al. suggest the transdermal delivery systems comprising 7α-methyl-19-nortestosterone, as discussed above.

29. Bardin et al. and Reed et al. do not suggest the use of the acetate salt of 7α-methyl-19-nortestosterone.

30. Moo-Young et al. teach the acetate salt of 7α-methyl-19-nortestosterone as preferred for use in an implantable system for subcutaneous or local administration of the androgen (claim 9; col. 3, lines 21-22).

31. It would have been obvious to the person of ordinary skill in the art at the time of invention to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Bardin et al. in view of Reed et al.

32. The person of ordinary skill in the art would have been motivated to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Bardin et al. in view of Reed et al. because Moo-Young et al. teach that this particular salt is preferred for implants which subcutaneously deliver the androgen. The person of ordinary skill in the art would have

expected success because both transdermal and subcutaneous delivery systems target the active agent to the skin. Thus, 7α-methyl-19-nortestosterone acetate would be expected to be effective in the transdermal systems suggested by Bardin et al. in view of Reed et al.

33. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US 5,780,050) in view of Bardin et al. (US 5,342,834) as applied to claims 1, 2-6, and 13-16 above, and further in view of Moo-Young et al. (US 5,733,565).

34. Jain et al. in view of Bardin et al. suggest transdermal delivery dosage forms comprising 7α-methyl-19-nortestosterone, as discussed above.

35. Moo-Young et al. teach the use of 7α-methyl-19-nortestosterone acetate as a preferred salt for local delivery of the androgen in the skin.

36. It would have been obvious to the person of ordinary skill in the art at the time of invention to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Jain et al. in view of Bardin et al.

37. The person of ordinary skill in the art would have been motivated to use 7α-methyl-19-nortestosterone acetate as the preferred salt of 7α-methyl-19-nortestosterone in the transdermal formulations suggested by Jain et al. in view of Bardin et al. because Moo-Young et al. teach that this particular salt is preferred for implants which subcutaneously deliver the androgen. The person of ordinary skill in the art would have expected success because both transdermal and subcutaneous delivery systems target

the active agent to the skin. Thus, 7α-methyl-19-nortestosterone acetate would be expected to be effective in the transdermal systems suggested by Jain et al. in view of Bardin et al.

Double Patenting

38. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

39. Claims 1, 3-16, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-23 of copending Application No. 10/741,207. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to transdermal delivery systems comprising 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate and methods of using said systems.

40. '207 teaches transdermal delivery systems comprising an androgen, including 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate, and methods of using said systems. The dose of the sex hormones in the systems of '207 is within the scope of the instantly claimed doses. Although '207 does not teach the flux of the transdermal dosage forms, this is an inherent property of the formulations.

41. '207 does not teach the preferred weight percent of the sex hormones in the formulation, but optimization of the weight percentage is a matter of routine experimentation for the ordinary skilled artisan. '207 also encompasses androgens other than 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate.

42. It would have been obvious to the person of ordinary skill in the art to select 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate as the preferred androgen and to optimize the weight of the formulation through routine experimentation to arrive at the instantly claimed inventions.

43. The person of ordinary skill in the art would have been motivated to select 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate because '207 teaches formulations comprising androgens. Thus, the person of ordinary skill in the art would expect 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate to be effective because it is an androgen. The person of ordinary skill in the art would have been further motivated to select 7α-methyl-19-nortestosterone or 7α-methyl-19-nortestosterone acetate as the androgen because they are exemplified as preferred androgens in claim 14.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

44. Applicant's arguments filed September 9, 2006, have been fully considered but they are not persuasive.

45. Regarding the rejection of claims 1 and 3-16 under 35 USC § 103 over Bardin et al. (US 5,342,834) in view of Reed et al. (WO 97/29735), Applicant argues that Bardin et al. suggest transdermal administration of 5 to 10 μg/kg of body weight of 7α-methyl-19-nortestosterone, which translates to a dose of 350 to 700 μg for a 70 kg patient, whereas the instant claims are directed to a formulation that delivers 400 to 1600 μg. The maintained rejections have been restated to reflect the fact that Applicant's position is understood. Specifically, Bardin et al. do not suggest a transdermal delivery device comprising a dose of 5 to 10 μg/kg of body weight of 7α-methyl-19-nortestosterone. They suggest that the dose delivered from the transdermal delivery system should be 5 to 10 μg/kg of body weight, which overlaps in the dose delivered from the instantly claimed transdermal delivery system. Thus, as stated above, determination of the amount of 7α-methyl-19-nortestosterone required in known transdermal delivery systems to deliver the dose of 7α-methyl-19-nortestosterone taught by Bardin et al. is a matter of routine experimentation and optimization for the ordinary skilled artisan.

46. Applicant further argues that Reed et al. give no guidance to the specific characteristics required in the transdermal system to achieve the herein-claimed flux

and amounts delivered. However, Reed et al. suggest that 7α-methyl-19-nortestosterone can be used in a variety of known transdermal delivery systems, including the herein-claimed forms. Reed et al. need not specify the exact composition of each an every transdermal delivery system with every possible drug listed because optimization of the amounts of the agents in the formulations to achieve a desired therapeutic dose is a matter of routine optimization. Further, it is noted that the instant claims do not have any limitation defining a specific transdermal delivery system that achieves the delivery of the desired dose. In other words, any transdermal system for delivering 7α-methyl-19-nortestosterone at the herein-claimed dose and flux is encompassed, which, as discussed throughout this and the previous action, would be a mater of routine optimization for the ordinary skilled artisan. Finally, although Applicant has submitted a Declaration to establish possession of the instantly claimed invention before the publication date of the Reed et al. reference, it is noted that Reed et al. list 20 other patents disclosing known transdermal delivery systems for delivery of agents such as 7α-methyl-19-nortestosterone (p. 7, lines 12-16).

47. Regarding the Examiner's reference to the MPEP and the assertion that the herein-claimed flux properties are inherent properties of the transdermal formulation rendered obvious by the combined teachings of the prior art, Applicant argues that this line of reasoning is inappropriate because this is not an anticipation rejection (see pp. 6-7 of Remarks). However, inherent properties are present in known products as well as products rendered obvious by the prior art. See MPEP § 2145, paragraph II, which states, "Granting a patent on the discovery of an unknown but inherent function...'would

re-move from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art'." Also see MPEP § 2112.01, paragraph I, which states, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established," (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)). This last section was cited in the previous Office Action but not addressed by Applicant.

48. Regarding the rejection of claims 1, 3-6, and 13-16 under 35 USC § 103 over Jain et al. (US 5,780,050) in view of Bardin et al. (US 5,342,834), Applicant argues that Jain et al. only disclose transdermal delivery of the genus of compounds, androgens, and does not recognize the herein-claimed non-5a-reducible androgens as being preferred in transdermal systems. Applicant asserts that Jain et al. is thus "non-anticipatory". It is noted that Jain et al. was not applied as an anticipatory reference. The Office Action even concedes Applicant's point–that Jain et al. do not teach the herein claimed non-5a-reducible androgens as being preferred in transdermal systems. Jain et al. broadly teach transdermal delivery systems comprising a genus of androgens encompassing the herein-claimed non-5a-reducible androgens. Bardin et al. teach that the non-5a-reducible androgen 7α-methyl-19-nortestosterone, which encompassed by the genus of Jain et al., is preferred in transdermal delivery systems. Thus, it would have been obvious to the person of ordinary skill in the art to incorporate 7α-methyl-19-nortestosterone into the transdermal delivery systems of Jain et al., and to optimize the

amount of 7α-methyl-19-nortestosterone in the system to achieve the therapeutic dose taught by Bardin et al. to arrive at the instantly claimed invention.

49. Regarding the rejections of claim 23 with the above-cited references with Moo-Young et al., applicant concedes that they have not invented the acetate salt of 7α-methyl-19-nortestosterone, and that the problem with these rejections is with the Bardin et al., Reed et al., and Jain et al. references. Thus, the response to the arguments provided above is seen to be sufficient in addressing the arguments against these rejections as well.

50. Applicant's assertion that the new Examiner has ignored the entire prosecution of the instant application is acknowledged. However, the current Examiner has not ignored the entire prosecution of the instant application. Specifically, a total of four Examiners have worked on this and the parent case 09/154,287. Upon reviewing the application files, it is clear that three of the four Examiners believed that the instantly claimed invention is not patentable over the art. Further, the previous Examiner made no statement on the record which clearly establishes the reasoning of why the instant claims are patentable over the art. In the Office Action mailed on October 25, 2005, the Examiner indicated that the claims drawn to a transdermal delivery system comprising 7α-methyl-19-nortestosterone as the active agent were allowable due to "evidence of unexpected results". It is unclear what "unexpected results" the Examiner was referring to. Most of the data presented compares the flux of 7α-methyl-19-nortestosterone to other testosterone derivatives in transdermal delivery systems. However, as was noted by the Examiner in the Office Action mailed on January 15, 2003, in the '287

application, 7α-methyl-19-nortestosterone was known to be preferred for use in transdermal delivery systems. Thus, although Applicant may have discovered that 7α-methyl-19-nortestosterone has greater flux in a transdermal delivery system than other testosterone derivatives, there was already sufficient motivation and expectation of success to formulate 7α-methyl-19-nortestosterone in known transdermal systems. See MPEP § 2145, paragraph II, which states, "The recitation of an additional advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention", and, "Granting a patent on the discovery of an unknown but inherent function...'would re-move from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art'", and, "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious."

51. Also, as noted throughout the prosecution history, optimization of the amount of 7α-methyl-19-nortestosterone in the transdermal systems to achieve the dose taught by Bardin et al. does not lend patentability to the instantly claimed formulation because it is a matter of routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Finally, as has also been noted throughout the prosecution history, the recitation of the flux of the agent from the transdermal system does not distinguish the instantly claimed invention from what is obvious from the prior art because it is an inherent property of the formulation that would have been arrived at by following the suggestions of the prior art and using routine optimization. Thus, in view of the fact that

all of these issues were raised by previous Examiners working on this application file, the current Examiner does not believe he is ignoring the entire prosecution history.

Conclusion

52. No claims are allowed.

53. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin Capps whose telephone number is (571) 272-8646. The examiner can normally be reached on Monday-Friday, 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER